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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,595	02/03/2004	Ashley Stuart Davis		1135
7590	03/15/2006		EXAMINER	
CYTOSKELETON INC. C/O ASHLEY DAVIS 1830 SOUTH ACOMA ST. DENVER, CO 80223			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,595	DAVIS ET AL.	
	Examiner David Lukton	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 6-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Pursuant to the directives of the response filed 12/27/05, claims 23-24 have been cancelled, and claim 20 amended.

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Claims 6-22 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 6 is indefinite as to the manifestations of “stability”. Is it reduction (or absence) of polymerization? Reduction of depolymerization? Absence of aggregation? Structural integrity? *In vitro* biochemical activity? Also, is it sufficient that one component of the composition be stabilized, e.g., the sucrose or the ATP...?
- In claim 7, the phrase “the composition of step (b)” lacks literal antecedent basis. The same issue applies in the case of claim 8. Perhaps the terms *first composition* and *second composition* could be used in some way. In response, applicants have argued that in claim 7, the term “the composition” refers to the pyrene actin composition which has been mixed with sucrose and a stabilizing agent. Applicants have further argued that there is no justification for the suggestion that the term “the composition” could refer to the pyrene actin composition prior to mixing with sucrose and a stabilizing agent. However, the examiner disagrees with applicants’ assessment. As it happens, there is nothing in claim 7 to preclude the possibility that the term “the composition” refers to the pyrene actin composition prior to mixing with sucrose and a stabilizing agent. Similarly, there is nothing in claim 8 to preclude the possibility that the term “the composition” refers to the pyrene actin composition prior to mixing with sucrose and a stabilizing agent.
- Claim 8 makes reference to a composition which has been frozen. Is a frozen composition an inherent feature of claim 6, or does one actually have to carry out the freezing process? The following is one option for claim language:

A process for stabilizing a pyrene actin composition comprising

- a) concentrating a pyrene actin composition, thereby generating a first pyrene actin composition;*
- b) mixing the first pyrene actin composition with sucrose and a stabilizing agent, thereby generating a second pyrene actin composition; and*
- c) rapidly freezing the second pyrene actin composition.*

- In claim 9, the phrase “said frozen composition” lacks literal antecedent basis. In response, applicants have argued that, while it is true that claim 8 does not recite the phrase “frozen composition”, its existence is implied by the language of claim 8. At the same time, applicants are unwilling to make explicit that which they regard as implicit. Such arguments that there are various hidden meanings does little to bolster applicants’ argument that the claims are clear and definite. Perhaps applicants believe that the composition of claim 6 is actually in the frozen state. What is there to preclude this possibility? If applicants are going to insist on using indefinite language, numerous possibilities arise as to alternative interpretations.
- In claim 12, it is unclear which of the various compositions is being referred to. Applicants have argued that the process of claim 12 means that the composition of claim 6 step b is being carried out pursuant to the process of claim 8. However, one could first freeze the composition of claim 6 pursuant to the method of claim 12, and subsequently freeze the composition of claim 6 pursuant to the method of claim 8. Or one could first freeze the composition of claim 6 pursuant to the method of claim 8, and subsequently freeze the composition of claim 6 pursuant to the method of claim 12. Then again, according to applicants, somewhere in the language of claim 8 there is a reference to a “frozen composition”. By applicants reasoning then, one could take the frozen composition of claim 8, which applicants have argued is present, and then rapidly freeze that in liquid nitrogen. This last possibility is indeed physically possible. For example, perhaps the “frozen composition” of claim 8 is at a temperature of -10 °C; placing the “frozen composition” of claim 8 in a liquid nitrogen bath will lower the temperature further. In any case,

applicants have attributed to the artisan of ordinary skill cognitive, and even telepathic powers which he does not actually possess.

- Claim 17 makes reference to “said pyrene actin composition”. Is this the composition of step (a) or the composition of step (b)...?
- Claim 18 makes reference to a concentration of sucrose. Is this the amount that is present after the mixing procedure of step (b), or was there some sucrose present before the mixing? The same issue applies in the case of claim 19. In response, applicants have argued that, somewhere in the language of claim 18, there is reference to a “final concentration” that is obtained after the process of claim 6, step (b) has been carried out. However, applicants are not correct. There is no such language in claim 18.
- Claim 20 makes reference to “A-buffer”. If this term is going to be used, it should be defined in the claims.
- In claim 20, the phrase “the lyophilized pyrene actin composition” lacks antecedent basis.
- In claim 20, the phrase “said resuspended pyrene actin composition” lacks antecedent basis.
- In claim 21, the phrase “said resuspended actin” lacks antecedent basis.
- In claim 22, the phrase “said resuspended actin” lacks antecedent basis.

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The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to

which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 6, 17, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Drenckhahn (*J. Biol. Chem.* 261, 12754, 1986).

Drenckhahn discloses methods of using pyrene-actin to study rates of elongation of pyrene-labelled filaments. Also disclosed (e.g., page 12755, col 1, paragraph 2) is that sucrose inhibit elongation of actin filaments.

The issue here pertains to the manifestations of "success" in achieving stability of the pyrene actin. Claim 6 can be interpreted to mean that the mere combination of pyrene actin with sucrose is tantamount to the attainment of stability, regardless of what experimentally manifest changes may occur in spite of the combination. In this respect, the requirements of the claim are met, since Drenckhahn does teach the requisite contacting step (pyrene-actin + sucrose).

Alternatively, claim 6 could be interpreted to mean that if polymerization of pyrene actin is reduced by the sucrose, the conditions of the claim are met. Even by this test, the disclosure of the reference qualifies.

Thus, the claim is rendered obvious.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER